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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,349	02/01/2002	John M. Pinney	6296.171	8964

7590

11/07/2003

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EXAMINER

CORBIN, ARTHUR L

ART UNIT	PAPER NUMBER
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1761

DATE MAILED: 11/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 10669349	Applicant(s) PINNEY ET AL
Examiner ARTHUR L. GIBLIN	Group Art Unit 1761

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

☒ Responsive to communication(s) filed on 8-1-02, 5-2-03

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 22-30 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 22-30 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement

Application Papers

- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☐ All ☐ Some* ☐ None of the:
 - ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 4
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

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1. In view of the papers filed August 1, 2002, the inventorship in this nonprovisional application has been changed by the deletion of Subraman Cherukuri and Aradhana Sasan.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 22-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Clarion 22-25 are indefinite in reciting "up to at least" (claim 22, line 4). Either "up to" or "at least" should be cancelled. Claim 23 is indefinite in failing to recite to whom the gum composition is administered.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 22-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferno et al (columns 2-4, 6-8 and 14).

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Ferno et al discloses a chewing gum composition for oral administration of nicotine including filler, sorbitol, sweetener, nicotine in the form of a nicotine complex, nicotine salt or nicotine base, a gum base matrix composed of polyvinyl acetate and another polymer and a buffer. The amount of nicotine in Ferno et al can be adjusted to give a quick release or slow release (column 3, line 68 to column 4, line 6). Since Ferno et al's composition includes each of applicant's claimed components it obviously will administer the nicotine in a bi-phasic manner as claimed by applicant. Finding the optimum release rate and effective concentration would require nothing more than routine experimentation by one reasonably skilled in his art.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 22-30 are also rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,344,222. Although the conflicting claims are not identical, they are not patentably distinct from each other because the gum composition claimed in 6,344,222 will obviously allow for ^a nicotine release rate as claimed by applicant since the

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components of said composition are the same as used by applicant to prepare the composition claimed herein.

8. Claims 22-30 are further rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27, 36-42 and 57-74 of U.S. Patent No. 6,358,060. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasoning set forth in paragraph No. 7 above.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cherukuri et al (4,971, 806) shows chewing gum having different release rates for active agents therein.

1. Any inquiry concerning this communication from the examiner should be directed to Arthur Corbin whose telephone number is (703) 308-3850. The examiner can generally be reached on Tuesday--Friday from 10 a.m. to 7:30 p.m. and on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (703) 308-3959. The fax phone numbers for the organization where this application is assigned are (703) 872-9310 for regular communications and (703) 305-7115 for After Final communications.

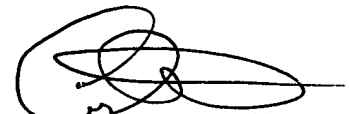
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Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0661.

A. Corbin/dh
November 3, 2003



ARTHUR L. CORBIN
PRIMARY EXAMINER
11-5-03